K100457

510(K) SUMMARY

ARTHROCARE CORPORATION
OPUS SPEEDSCREW SYSTEM

MAR 19 2010

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration No.:	2951580
Contact Person:	Laura N. Kasperowicz Sr. Manager, Regulatory Affairs
Date Prepared:	February 12, 2010

Device Description

Trade Name:	
Device Model Name:	Opus SpeedScrew System
Generic/Common Name:	Bone Anchor
Classification Name:	Screw, Fixation, Bone (Class II per 21 CFR 888.3040, Product code: HWC)

Predicate Devices

Opus SpeedScrew	K081893 (Cleared October 1, 2008)

Product Description

The SpeedScrew Knotless Fixation Device is an implant that facilitates the attachment of tissue to bone. The SpeedScrew implant is a knotless fixation device, in other words surgical knots are not necessary for fixation of suture to tissue. The Opus SpeedScrew System consists of an implant and associated instruments for installation of the implant that is designed for specific indications in arthroscopic and orthopedic procedures.

Indications For Use

The SpeedScrew Knotless Fixation Device is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon attachment
Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

510(K) SUMMARY

Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The SpeedScrew System design and technology is substantially equivalent to the existing SpeedScrew System cleared by the Food and Drug Administration (K081893). The differences between the SpeedScrew System and the predicate system do not raise questions regarding the safety and effectiveness of the implant. The proposed system, as designed, is as safe and effective as the predicate system.

Summary and Reason for 510k Notification

For the purpose of this premarket notification [510(k)], ArthroCare proposes additional ancillary instrumentation to be used in conjunction with an existing bone anchor cleared under the trade name, Opus SpeedScrew Knotless Fixation Device originally cleared under K081893.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2010

ArthroCare Corporation
% Ms. Laura N. Kasperowicz
Sr. Manager, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

Re: K100457
Trade Name: Opus SpeedScrew System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 12, 2010
Received: February 17, 2010

Dear Ms. Kasperowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K100457

Device Name: Opus SpeedScrew System

Indications for Use:

The SpeedScrew Knotless Fixation Device is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon attachment
Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	NO

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100457